REMARKS

Applicants wish to thank the Examiner for taking the time to conduct a telephone interview on Tuesday, 18 September, with the undersigned and Drs. Roger Sabbadini and Laurel Bernstein of Lpath, Inc. Based on that interview, Applicant has elected to make certain claim amendments. Specifically, upon entry of the amendment above, claims 1-28 will be cancelled in favor of new claims 29-42. As a point of clarification, original claim 17 was previously cancelled (see Applicant's response filed 21 February 2007), although the Final Office action dated 30 March 2007 indicates that this claim is pending.

During the recent telephonic interview, the Examiner requested that Applicant update the continuing information in the specification. Herein, Applicant has also included a corresponding amendment to update this portion of the application.

Applicant acknowledges that priority has been granted to 22 December 2000.

To expedite consideration of this application, Applicant notes that the claimed methods now focus on certain preferred embodiments, namely treatment of acute myocardial ischemic events and their sequelae in mammals, including humans. No new matter has been added, and the foregoing amendments are not being made for purposes of patentability, but to advance prosecution by focusing on particular commercially relevant embodiments of Applicant's pioneering invention. Each of the new claims is fully supported by the specification and claims as originally filed. In any event, for the record, Applicant reserves the right to pursue no longer or not yet claimed inventive subject matter in this or a related application.

Applicant respectfully requests reconsideration in view of the following arguments.

35 U.S.C. §102(a) - Novelty

Claims 1-8, 15-17, 19, and 21 stand rejected as being anticipated by each of U.S. patent nos. 6,649,362 (Gamble) and 6,613,322 (Tabas). Claims 1-8, 15-17, 19, and 21 have now been cancelled in favor of several new claims in order to expedite prosecution and more precisely focus examination on particularly important aspects of the invention. In particular, the new claims focus on methods for treating acute myocardial ischemic events in mammals, including humans, who are known or suspected to be suffering or have suffered such an event. Support for this amendment is found throughout the specification, including at page 9, paragraph 1, and page 16, paragraph 3. In other words, the claims of this application no longer focus generally on

methods for treating or preventing ischemia or hypoxia in mammals; instead, the new claims are drawn specifically to methods for treating acute myocardial ischemia, which, for example, can result from a restriction in or deficiency of oxygenated blood flow in or to the myocardium (heart muscle tissue). The instant methods can be performed, for example, to limit further damage caused by the acute ischemic event. Damage associated with such an acute ischemic event can include sudden cardiac death, myocardial tissue damage, myocardial cell death, reperfusion damage, myocardial infarction, or heart failure. Applicant respectfully submits that these methods are patentably distinct from prevention or treatment of chronic vascular conditions such as coronary heart disease, also known as coronary artery disease, which is an obstruction of the arteries that supply the heart due to gradual accumulation of atherosclerotic plaques over time. Accordingly, neither the '362 nor '322 patent teaches each and every element of Applicant's claimed invention, as neither suggests, let alone teaches, a method for treating an acute myocardial ischemic event in an animal, such as a human. As such, neither the '362 nor '322 patent can anticipate the claimed invention. Accordingly, this rejection should be withdrawn.

35 U.S.C. §103(a) – Non-obviousness

Claims 22-28 stand rejected as being obvious in view of a combination of the '362 and '322 patents. Claims 22-28 have also now been cancelled. As explained above, neither of the cited patents teaches the treatment of acute myocardial ischemic events in an animal, and thus even if they may be combined (a point Applicant reserves the right to contest), they do not teach or suggest any method claimed herein. Accordingly, this rejection should also be withdrawn.

For completeness, Applicant wishes to respond to the assertion in the most recent Office action that "some of the claimed compounds such as sodium fluoride, propranolol, and others are known to be administered to humans for various reasons and treating vascular disease would have been inherent in administering the same compounds for any reason." To the extent this assertion may be relevant to any of the new claims added by way of the amendment above, Applicant notes that the burden is on the Office to provide rationale or evidence for inherency. *See* MPEP 2112. No such rationale or evidence appears to have yet been presented. Furthermore, Applicant claims methods for treating acute myocardial ischemic events, not methods for treating vascular disease in general. For these reasons, Applicant requests that this rejection also be withdrawn.

35 U.S.C. §112, First Paragraph – Written Description and Enablement

Claims 1-8, 15-17, 19, and 21-28 stand rejected as failing to comply with the "written description" and "enablement" requirements of 35 U.S.C. §112, first paragraph. As these claims have now been cancelled, these rejections are moot. To avoid its extension to any of new claims 29-42, however, Applicant notes that the new claims do not concern methods wherein the agents are not aminoglycosides, nor are they directed to methods of prevention. Instead, the new claims concern methods of treatment of acute myocardial ischemic events in mammals. These methods comprise administering a therapeutically effective amount of an agent to a mammal known or suspected to be suffering or to have suffered an acute myocardial ischemic event, wherein the agent is a small molecule, protein, polypeptide, or polypeptide derivative that alters the activity or concentration of an enzyme that catalyzes a reaction that produces or degrades a sphingolipid or a sphingolipid metabolite. Also, to the extent the new claims address "prevention", it is in the context of preventing damage caused by an acute myocardial ischemic event, not in preventing the occurrence of acute myocardial ischemic event itself.

35 U.S.C. §112, Second Paragraph

Each of claims 1-8, 15-17, 19, and 21-28 also stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite due to the use of the indefinite article "A" instead of the definite article "The" in the preamble of the dependent claims. Applicant respectfully traverses, for two reasons. First, the bases for this rejection have been obviated by the cancellation of these claims. Because the dependent claims among new claims 29-42, however, also recite "A method …" as opposed to "The method …", Applicant's second point is that there is no requirement, in Title 35 of the U.S. Code, 37 C.F.R., or the MPEP that requires particular wording of the sort suggested by the Examiner. Indeed, the use of the claim format chosen by Applicant is shown in MPEP 608.01(n) and thus should be acceptable. For these reasons Applicant respectfully asks that this rejection also be withdrawn.

Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance, and earnestly solicits prompt issuance of a notice to such effect. Of course, if any issue remains

outstanding that may be addressed without the need for an additional formal action and response thereto, the Examiner is encouraged to telephone the undersigned in order to resolve such issue(s).

Respectfully submitted,

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By: /Daniel M. Chambers/
Daniel M. Chambers
Attorney for Applicant
BioTechnology Law Group
Reg. No. 34,561
Tel: 858.350.9690